

**CORPORATE INTEGRITY AGREEMENT**  
**Between The**  
**Office of Inspector General**  
**Of The**  
**Department of Health and Human Services**  
**And**  
**Brigham & Women's Hospital Pathology Foundation, Inc.**

This Corporate Integrity Agreement is entered into between Brigham and Women's Hospital Pathology Foundation, Inc. ("Brigham Pathology Foundation"); and the Office of Inspector General ("OIG") of the Department of Health and Human Services ("HHS"). Pursuant to this Agreement, Brigham Pathology Foundation agrees to undertake the compliance provisions outlined below.

**I. PREAMBLE**

Brigham Pathology Foundation agrees to implement this Corporate Integrity Agreement (the "Agreement") so as to ensure, to the extent reasonably possible, that Brigham Pathology Foundation and each of its Board of Directors, officers, employees and contractors maintain the business integrity required of a participant in Medicare, Medicaid and other federal health care programs, as defined in 42 U.S.C. 1320a-7b(f), and that Brigham Pathology Foundation is in compliance with all laws and regulations applicable to such programs and with the terms of this Agreement. The period of future integrity obligations assumed by Brigham Pathology Foundation under this Agreement shall be three (3) years from the date of execution of this Agreement. The date of execution of this Agreement is the date the final signature is obtained.

**II. CORPORATE COMPLIANCE PROGRAM**

Brigham Pathology Foundation agrees to continue to implement and maintain its voluntary "Corporate Compliance Program" which has been adopted by Brigham Pathology Foundation's Board of Directors. This document is attached to this Agreement, and incorporated by reference, as Attachment A. To the extent that any of the obligations required by this Agreement replicate provisions contained in the attached Corporate Compliance Program, those provisions are deemed acceptable for the purpose of Brigham Pathology Foundation meeting its obligations under this Agreement.

### **III. CORPORATE INTEGRITY PROGRAM**

Within one hundred twenty (120) days of the date of execution of this Agreement, Brigham Pathology Foundation agrees to implement a Corporate Integrity Program (the "Program"), which shall include the provisions listed herein.

#### **A. Corporate Compliance Committee and Corporate Compliance Officer**

Within ninety (90) days of the date of execution of this Agreement, the Board of Directors of Brigham Pathology Foundation shall: (i) direct the creation of a Corporate Compliance Committee (the "Compliance Committee"); (ii) charge the Compliance Committee with the responsibility to establish and implement the Program; and (iii) appoint an individual to serve as the Compliance Officer ("CO").

The members of the Compliance Committee shall be appointed by the President of Brigham Pathology Foundation, and shall include the Compliance Officer, the Brigham Pathology Foundation's Administrator, and any others that Brigham Pathology Foundation deems appropriate.

The Compliance Officer shall chair the Compliance Committee and shall be responsible for the day-to-day activities engaged in by Brigham Pathology Foundation to further the operations of the Program.

The Compliance Officer shall submit annual reports to OIG's Office of Counsel to the Inspector General ("OIG") of the United States Department of Health and Human Services ("HHS"), in accordance with the terms of this Agreement.

#### **B. Audit Requirement**

Beginning on the effective date of this Agreement and continuing for the duration of the term of this Agreement, Brigham Pathology Foundation shall conduct ongoing audits in accordance with the following protocol:

1. Each week, a printout of all professional fee charges generated by the Foundation will be delivered to Pathology Administration before any final bills are generated. Each week, an administrator will review selected cases from the weekly printout for any potential charge code errors. The administrator shall select cases for review based upon the criteria described below. The risk areas shall be selected according to greatest risk, with a. being the greatest risk and f. presenting the least risk. In accordance with this Agreement,

Brigham Pathology Foundation will review all cases in categories a. and b. Brigham Pathology Foundation will select random samples, with a minimum of ten cases per category, or the number of cases in the category, whichever is less, for categories c. through f. Cases selected for review under this section may include cases selected for administrative review as described in section III. B. 2.

- a. error codes stemming from the data transmission from the Brigham & Women's Hospital computer system to the Pathology Foundation computer system;
  - b. Cases that have more than three (3) dissimilar specimen types;
  - c. Cases that incorporate the highest level fee codes, whether singly or in conjunction with other specimens;
  - d. Cases that have multiple charge codes for other services, such as frozen sections, special stains, decalcification of specimens, immunohistochemistry, etc.;
  - e. Cases selected at random of different specimen types, especially those where there are unique rules as to the selection of proper codes (e.g., hysterectomy cases and the bundling of specimens); and
  - f. Cases that have lower level charge codes, either in multiple units or singly.
2. Each week, a Foundation administrator also will review all cases flagged for administrative review by senior staff at the time of final case sign-out.
  3. If there is any uncertainty about the correctness of the coding of a particular case, a physician reviewer in the Foundation will review the coding of a case and report back his/her opinion to the administrator, who will modify the charge coding, if necessary. An expert consultant also will be used on those occasions where more general clarification is needed on coding situations across a number of case types.
  4. If any incorrect charges are identified during a particular case review, a list of those charges will be prepared and faxed to the

billing agent for the Foundation to correct the charges on that case before a bill is sent out.

5. At least bi-annually, the administrator or compliance officer (or designee) will review a sample of the faxed corrections to ensure that all billing documents were corrected prior to submission of the claim.
6. Follow-up communication as appropriate will be made to the physician or technical staff on coding errors discovered at time of case review, providing explanations of the error and suggesting steps to prevent future problems. This is part of the Foundation's on-going training in proper coding for staff as part of Foundation's Compliance Plan.
7. The Foundation will maintain detailed logs of all cases reviewed and the results of that review.
8. The central charge coding reviewer will, on an ongoing basis, validate the fee codes assigned to high risk cases, such as those with multiple frozen sections and/or multiple charge level V or VI parts. Charge errors, if any, will be corrected immediately by the reviewer. The reviewer will also report to the Compliance Officer regarding any trends or consistent errors that have been detected, and the Compliance Officer and administrator will initiate immediate corrective action as indicated.
9. A formal randomized sample of one hundred (100) Medicare/Medicaid patient records completed but not yet billed as of the concurrent audit date will be selected from all those available during the first week of each April and October. The complete pathology report, the interim patient account record, the pathology consult requisition, and any other backup (e.g., pathologist intra-operative consult record, order for special stains, etc.) will be gathered together for each sampled patient record. All 100 patient records will initially be validated by the central charge coding reviewer, who will then turn over the complete record set and his findings with respect to each to an outside auditor. The outside auditor will independently verify the accuracy of the fee codes and the ICD-9-CM diagnosis codes assigned to each case, and he/she will immediately report any exception(s) to the Compliance Officer for corrective action as indicated. All of these actions will be

undertaken and completed prior to release of any of the 100 patient records for formal claim preparation and filing.

10. Immediately after the release of the preceding 100 patient records for claim preparation, hard copy reproduction of each such claim will be forwarded to the outside auditor. He/she will verify the efficacy of all claims, consisting of key data fields such as name of referring physician; disclosure of the identification number of the performing pathologist; correct ICD-9-CM and CPT billing codes and correct units of service per CPT billing code as determined by the previous audit step; correct CPT code modifier use; correct CPT number; and proper disclosure of Graduate Medical Education resident involvement in the case, as applicable. The outside auditor will promptly report the results of his/her review to the Compliance Officer, who in turn will initiate any corrective action as may be indicated.
11. The concurrent audit for each October will also include a post-payment review step. In particular, the outside auditor will conduct a detailed analysis of each patient account subject to the random sample steps set forth above. The analysis will assure proper filing on behalf of any secondary insurance and/or patient billing pertaining to deductible and/or coinsurance amounts. It will also verify that the Medicare Part B carrier paid the correct amount for the claim and that it properly and accurately adjudicated each account. The outside auditor will promptly report the results of his/her review to the Compliance Officer, who in turn will initiate any corrective action as may be indicated. Also, the Compliance Officer will modify the training and education program as appropriate in response to these audits.

**C. Overpayments and Material Deficiencies**

If, as a result of these audits, Brigham Pathology Foundation identifies any billing, coding or other policies, procedures and/or practices that result in an overpayment, Brigham Pathology Foundation shall notify the payor (e.g., Medicare fiscal intermediary or carrier) within 30 days of discovering the deficiency or overpayment and take remedial steps within 60 days of discovery (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the deficiency from recurring. The notice to the payor shall include:

1. a statement that the refund, if appropriate, is being made pursuant to this CIA;
2. a description of the complete circumstances surrounding the overpayment;
3. the methodology by which the overpayment was determined;
4. the amount of the overpayment;
5. any claim-specific information used to determine the overpayment (e.g., beneficiary health insurance number, claim number, service date, and payment date); and
6. the provider identification number under which the repayment is being made.

If Brigham Pathology Foundation determines an overpayment represents a material deficiency, contemporaneous with Brigham Pathology Foundation's notification to the payor as provided above, Brigham Pathology Foundation shall also notify OIG of:

1. a complete description of the material deficiency;
2. amount of overpayment due to the material deficiency;
3. Brigham Pathology Foundation's action(s) to correct and prevent such material deficiency from recurring;
4. the payor's name, address, and contact person where the overpayment was sent;
5. the date of the check and identification number (or electronic transaction number) on which the overpayment was repaid.

For purposes of this CIA, an "overpayment" shall mean the amount of money the provider has received in excess of the amount due and payable under the Federal health care programs' statutes, regulations or written program directives, and/or carrier and intermediary instructions.

For purposes of this CIA, a "material deficiency" shall mean anything that involves: (i) a substantial overpayment or improper payment relating to the Medicare and/or Medicaid programs; (ii) conduct or policies that clearly

violate the Medicare and/or Medicaid statute, regulations or directives issued by HCFA and/or its agents; or (iii) serious quality of care implications for federal health care beneficiaries or recipients. A material deficiency may be the result of an isolated event or a series of occurrences.

**D. Corporate Integrity Policy**

Within one hundred twenty (120) days of the date of execution of this Agreement, Brigham Pathology Foundation shall develop and implement written policies regarding its commitment to accurate billings consistent with published Medicare and Medicaid statutes, regulations, program requirements and other written directives from HCFA or its agents.

These policies shall be adopted by Brigham Pathology Foundation's Board of Directors and distributed to all employees and independent contractors involved in submitting or preparing bills or claims on behalf of Brigham Pathology Foundation to the Medicare, Medicaid or other federal health care programs. Brigham Pathology Foundation shall post in a prominent place accessible to each employee a notice detailing its commitment to comply with all applicable Medicare, Medicaid and other federal health care programs' statutes, regulations, written directives and program requirements in the conduct of its business. A copy of the policies and notices will be available, upon request, for review by OIG or its duly authorized representative.

**E. Information and Education**

Within one hundred twenty (120) days of the date of execution of this Agreement, Brigham Pathology Foundation shall develop and institute an information and education program designed to ensure that each officer, Board of Directors member and employee who is involved directly or indirectly in the preparation or submission of claims for reimbursement to the Medicare, Medicaid and other federal health care programs is aware of all applicable statutes, regulations and written HCFA directives. The information and education program should also convey the standards of business conduct that each individual is expected to follow and the consequences both to the individual and Brigham Pathology Foundation that will ensue from any violation of these requirements.

The information and education program shall provide for no less than three (3) hours of formal training on an annual basis in: (i) the Corporate Integrity Program; (ii) the submission of accurate bills for services rendered to Medicare, Medicaid and other federal health care program patients; (iii)

the personal obligation of each individual involved in the billing process to ensure that such billings are accurate; (iv) applicable reimbursement rules and laws; and (v) the legal sanctions for improper billings and examples of improper billing practices. Information concerning the format, dates, and a copy of the materials provided will be available, upon request, for review by OIG. Individuals whose contact with the billing process is both indirect and tangential, such as secretarial staff, are not required to have three (3) hours of training, but must have at least one and one-half hours of training (as described in this paragraph) per year.

The above-described training requirements shall be included in the formal orientation for new officers, Board of Directors members and staff (residents and any other hospital employees) who perform services on behalf of Brigham Pathology Foundation.

**F. Confidential Disclosure Program**

Within ninety (90) days of the date of execution of this Agreement, Brigham Pathology Foundation shall establish a confidential disclosure program enabling members, employees, contractors and physicians with staff privileges to disclose any practices or billing procedures alleged by such person to be inappropriate, to an identified individual not in that person's direct chain of command. Brigham Pathology Foundation shall, as part of this disclosure program, require the internal review of any disclosure that is sufficiently specific so that it: (i) permits a determination of the appropriateness of the practice alleged to be involved; and (ii) reasonably permits corrective action to be taken and ensure that proper follow-up is conducted. In an effort to address every disclosure, Brigham Pathology Foundation shall make a good faith preliminary inquiry for every disclosure instance to ensure that it has obtained all of the necessary information that is reasonably required to determine whether an internal review, in accordance with the language above, should be conducted. Brigham Pathology Foundation agrees that it will not take any retaliatory or adverse actions against any member, employee, contractor or physician with staff privileges who makes a confidential disclosure and that, to the extent possible, it will protect the anonymity of the person making the disclosure. This section does not preclude Brigham Pathology Foundation from taking disciplinary action (up to and including termination) against a member, employee, contractor or physician with staff privileges for actions or conduct unrelated to the making of the confidential disclosure.

Brigham Pathology Foundation shall include in its Annual Report to OIG a summary of communications received from the Confidential Disclosure



Program and the findings of any investigations performed as a result of these disclosures. Brigham Pathology Foundation shall make the results of the investigations available to OIG upon its request. At OIG's option, OIG may also review the documentation on Brigham Pathology Foundation's premises. In turn, Brigham Pathology Foundation agrees to maintain such reports in a manner agreeable to OIG so that they will be readily available to OIG for a minimum of one (1) year longer than the duration of this Agreement.

**G. Ineligible Persons**

For purposes of this CIA, an "Ineligible Person" shall be any individual or entity who: (i) is currently excluded, suspended, debarred or otherwise ineligible to participate in the Federal health care programs; or (ii) has been convicted of a criminal offense related to the provision of health care items or services and has not been reinstated in the Federal health care programs after a period of exclusion, suspension, debarment, or ineligibility.

Brigham Pathology Foundation shall not hire or engage as contractors any Ineligible Person. To prevent hiring or contracting with any Ineligible Person, Brigham Pathology Foundation shall screen all prospective members, employees, and contractors prior to engaging their services and screen physicians prior to granting staff privileges by (i) requiring applicants to disclose whether they are Ineligible Persons, and (ii) reviewing the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at <http://www.arnet.gov/epl>) and the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://dhhs.gov/progorg/oig>) (these lists and reports will hereinafter be referred to as the "Exclusion Lists").

Within ninety (90) days of the effective date of this CIA, Brigham Pathology Foundation will review its list of current members, employees, contractors and physicians with staff privileges against the Exclusion Lists. Thereafter, Brigham Pathology Foundation will review the list once semi-annually. If Brigham Pathology Foundation has notice that a member, employee, contractor, or physician with staff privileges has become an Ineligible Person, Brigham Pathology Foundation will remove such person from responsibility for, or involvement with, Brigham Pathology Foundation's business operations related to the Federal health care programs and shall remove such person from any position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health

care programs or otherwise with Federal funds at least until such time as the person is reinstated into participation in the Federal health care programs.

If Brigham Pathology Foundation has notice that a member, employee, contractor or physician with staff privileges is charged with a criminal offense related to any Federal health care program, or is suspended or proposed for exclusion during his or her employment or contract with Brigham Pathology Foundation, within 10 days of receiving such notice Brigham Pathology Foundation will remove such individual from responsibility for, or involvement with, Brigham Pathology Foundation's business operations related to the Federal health care programs until the resolution of such criminal action, suspension, or proposed exclusion.

Brigham Pathology Foundation shall not knowingly allow, or cause to be allowed, any person convicted in any local, state or federal court of any felony involving health care matters to hold the position of officer or member of the Board of Directors of Brigham Pathology Foundation, or any of its subsidiaries either through an employment agreement or an independent contract.

Should Brigham Pathology Foundation discover that it has employed an individual, allowed a physician to become a member, granted staff privileges to a physician or entered into a consultant agreement in contravention of this provision, Brigham Pathology Foundation will have thirty (30) days to take the necessary steps to cure the problem, in accordance with this section,

#### **H. Reporting on Investigations**

Within fourteen (14) days of becoming aware of the existence of any investigation or legal proceeding conducted or brought by a governmental entity involving an allegation that Brigham Pathology Foundation has committed a crime or has engaged in fraudulent activities, Brigham Pathology Foundation shall notify OIG of such investigation or legal proceeding. The notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. Within fourteen (14) days of the resolution of the investigation or legal proceeding, Brigham Pathology Foundation shall notify OIG, identifying the findings or results of the investigation or legal proceeding.

#### **IV. OIG INSPECTION, AUDIT AND REVIEW RIGHTS**

In addition to any other right OIG may have by statute, regulation, contract or pursuant to this Agreement, OIG or its duly authorized representative(s) may examine Brigham Pathology Foundation's books, records, and other company documents and supporting materials for the purpose of verifying and evaluating: (i) Brigham Pathology Foundation's compliance with the terms of this Agreement; and (ii) Brigham Pathology Foundation's compliance with the requirements of the Medicare, Medicaid and other federal health care programs. The documentation described above shall be made available by Brigham Pathology Foundation at all reasonable times for inspection, audit or reproduction. Furthermore, for purposes of this provision, OIG or its authorized representative(s) may interview any of Brigham Pathology Foundation's employees, members or physicians with staff privileges who consent to be interviewed at the Department of Pathology of Brigham and Women's Hospital during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. Brigham Pathology Foundation agrees to cooperate with OIG in contacting and arranging interviews with such individuals upon OIG's request. Individuals may elect to be interviewed with or without a representative of Brigham Pathology Foundation present.

#### **V. REPORTS**

The CO of Brigham Pathology Foundation shall be responsible for the submission of all reports and notifications to OIG as required by this Agreement.

##### **A. Interim Report**

Within one hundred eighty (180) days of the date of execution of this Agreement, Brigham Pathology Foundation will provide OIG with an Interim Report demonstrating that Brigham Pathology Foundation has complied with all of the Program's requirements contained in Sections III. A, C, D, E, and F of this Agreement. The Interim Report shall also identify the Compliance Officer and the members of the Compliance Committee and identify the steps taken to comply with Section III. B of this Agreement.

##### **B. Annual Reports**

Brigham Pathology Foundation shall make Annual Reports (each one of which is referred to throughout this Agreement as the "Annual Report") to OIG describing the measures Brigham Pathology Foundation has taken to implement the Corporate Integrity Program and ensure compliance with the

terms of this Agreement. In accordance with the provisions above, the Annual Report shall include the following:

1. In the first Annual Report, copies of the document or documents that comprise Brigham Pathology Foundation's Corporate Integrity Program established under section III. of this Agreement as adopted by Brigham Pathology Foundation's Board of Directors and implemented by the Corporate Compliance Committee. For subsequent years, Brigham Pathology Foundation shall note in the Annual Report any amendments or revisions to the Program documents made during the year covered by the Annual Report.
2. A detailed description of the findings made during the annual audits conducted pursuant to section III. B. of this Agreement relating to the year covered by the Annual Report, a summary of the disclosure or notice documents made by Brigham Pathology Foundation pursuant to this section, a description of the corrective actions taken and proof of a refund to the pertinent payor (where applicable).
3. A description of the training programs implemented pursuant to section III. E. of this Agreement and a summary of the activities performed in furtherance of the training programs, including a schedule and topic outline of the training sessions.
4. A summary of communications received from the Confidential Disclosure Program established pursuant to section III. F. and the results of any investigations performed as a result of any disclosures.
5. A summary of the background inquiries conducted pursuant to section III. G. of this Agreement and any personnel actions taken (other than hiring) as a result of these inquiries.
6. A summary of any ongoing investigation or legal proceeding conducted or brought by a governmental entity involving an allegation that Brigham Pathology Foundation has committed a crime or has engaged in fraudulent activities. The statement shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding as required by section III. H. of this Agreement.
7. The names of Brigham Pathology Foundation's officers, members of the Board of Directors and Compliance Committee members.

8. A resolution (or its equivalent) from Brigham Pathology Foundation's Board of Directors certifying that it has reviewed the Annual Report and agrees with the statements made therein.

Where applicable, the report shall include a statement that no events identified in subparagraphs 1 through 6 of this section occurred. Each Annual Report shall be submitted to OIG one hundred twenty (120) days after the end of the fiscal years ending June 30, 2000, 2001 and 2002. The obligation to submit the last Annual Report will continue despite the other obligations of this Corporate Integrity Agreement having terminated under section I. of this Agreement.

## **VI. NOTIFICATION AND SUBMISSION OF REPORTS**

Unless otherwise stated, subsequent to the execution of this Agreement, all notifications and reports required under the terms of this Agreement shall be submitted, in writing, to the following:

If to OIG:

U.S. Department of Health and Human Services  
Office of Counsel to the Inspector General  
Civil Recoveries Branch - Compliance Unit  
330 Independence Avenue, SW  
Cohen Building, Room 5527  
Washington, D.C. 20201  
Telephone: 202.619.2078  
Fax: 202.205.0604

If to Brigham Pathology Foundation:

Dr. Frederick J. Schoen  
Corporate Compliance Officer  
Brigham & Women's Hospital Pathology Foundation  
75 Francis Street  
Boston, Massachusetts 02115  
Telephone: 617.732.5709  
Fax: 617. 232.9820  
Medicare Provider Number:

## **VII. DOCUMENT AND RECORD RETENTION**

Brigham Pathology Foundation shall maintain for inspection, documents and records relating to the following: (i) Medicare, Medicaid and other federal health care programs reimbursement; and (ii) its obligations under the terms of this Agreement, for one year longer than the duration of this Agreement, or longer if otherwise required by law, following the execution of this Agreement.

## **VIII. STIPULATED PENALTIES**

Brigham Pathology Foundation's compliance with the terms and conditions of this Agreement shall constitute an element of Brigham Pathology Foundation's present responsibility with regard to participation in Medicare, Medicaid and other federal health care programs. Pursuant to section XVI. of this Agreement, any and all modifications to this Agreement (including changes to dates on which an obligation is due to be met) shall be requested in writing and agreed to by OIG in writing prior to the date on which the modification is expected to take effect. Absent such written modifications, Brigham Pathology Foundation agrees to the following stipulated penalties.

- A. Brigham Pathology Foundation shall pay a stipulated penalty of \$2,500 for each day it fails to comply with any of the following terms, which stipulated penalty shall begin to accrue one day after the date the obligation becomes due.
  - 1. The creation of a Corporate Compliance Committee and the appointment of Corporate Compliance Officer within ninety (90) days of the execution of this Agreement.
  - 2. Submission of the Interim Report within one hundred eighty (180) days of the execution of this Agreement.
  - 3. Submission of the Annual Report by the due date required in section V. of this Agreement.
  - 4. Establishment of a confidential disclosure program within ninety (90) days of the execution date of this Agreement.
- B. A stipulated penalty of \$2,500 for each day Brigham Pathology Foundation fails to comply by having fully in force during the term of this Agreement any of the following, which stipulated penalty shall begin to accrue on the date of receipt of the OIG's notice of noncompliance or as otherwise indicated in OIG's notice in accordance with section IX. below.

1. Implementation and maintenance of the written Corporate Integrity Policy, as required by section III. D. of this Agreement.
  2. Granting access to the information or documentation necessary to exercise OIG's inspection, audit and review rights, as set forth in section IV. of this Agreement.
  3. Implementation and maintenance of the information and education program, as required by section III. E. of this Agreement.
  4. Notification to OIG of the existence or conclusion of any investigation or legal proceeding, as required by section III. H. of this Agreement.
- C. Brigham Pathology Foundation shall pay a stipulated penalty of \$1,500 for each day it knowingly employs or contracts with or grants staff privileges to an Ineligible Person and that person: (i) has responsibility for, or involvement with, Brigham Pathology Foundation's business operations related to the Federal health care programs or (ii) is in a position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds (this Stipulated Penalty shall not be demanded for any time period during which Brigham Pathology Foundation can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in section III.G) as to the status of the person).
- D. A Stipulated Penalty of \$500 (which shall begin to accrue ten (10) days after the date that OIG provides written notice by certified mail to Brigham Pathology Foundation of the failure to comply) for each day Brigham Pathology Foundation fails to comply fully and adequately with any other obligation of this CIA. In its notice to Brigham Pathology Foundation, the OIG shall state the specific grounds for its determination that the Brigham Pathology Foundation has failed to comply fully and adequately with the CIA obligation(s) at issue.

## **IX. PAYMENT OF STIPULATED PENALTIES**

Upon finding that Brigham Pathology Foundation has failed to comply with any of the above-enumerated obligations, OIG shall notify Brigham Pathology Foundation by certified mail of: (i) Brigham Pathology Foundation's failure to comply; and (ii) OIG's exercise of its contractual right to demand payment of the

stipulated penalties payable under this Agreement (this letter is hereinafter referred to as the "Demand Letter"). The applicable stipulated penalties shall begin to accrue on the date specified in section VIII., which date shall be indicated in the Demand Letter.

Within thirty (30) days of the receipt of the Demand Letter, Brigham Pathology Foundation shall do either of the following: (i) cure the breach to the OIG's satisfaction and pay the applicable stipulated penalties; or (ii) request a hearing before an HHS administrative law judge to dispute the OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth in section XI. of this Agreement. Failure to respond as required above shall constitute a material breach of this Agreement, as set forth in section X. of this Agreement.

Payment of the stipulated penalties shall be made by certified or cashier's check, payable to "Secretary of the Department of Health and Human Services," and submitted to OIG at the address set forth in section VI. of this Agreement.

These provisions for payment of stipulated penalties shall not affect or otherwise set a standard for the OIG's determination that Brigham Pathology Foundation has materially breached this Agreement, which decision shall be made at the OIG's discretion and governed by the provisions in section X. of this Agreement.

If OIG makes a determination to impose stipulated penalties in accordance with this provision, Brigham Pathology Foundation shall have the right to dispute OIG's determination in accordance with the agreed upon provisions set forth in section XI. of this Agreement.

## **X. REMEDY FOR MATERIAL BREACH OF THIS AGREEMENT**

If Brigham Pathology Foundation engages in conduct that OIG determines to be a material breach of this Agreement, OIG may seek an enhanced stipulated penalty of \$10,000 per day for each day Brigham Pathology Foundation is determined to be in material breach of this Agreement. Upon making its determination, OIG shall notify Brigham Pathology Foundation of the alleged material breach by certified mail and of its intent to impose this enhanced stipulated penalty as a result thereof (this letter shall be referred to hereinafter as the "Intent to Impose an Enhanced Stipulated Penalty Letter"). Brigham Pathology Foundation shall have thirty-five (35) days from the date of receipt of the letter to proceed as follows:

- (1) cure the alleged material breach; or



- (2) demonstrate to the OIG's satisfaction that: (a) Brigham Pathology Foundation is in full compliance with this Agreement; or (b) the material breach cannot be cured within the thirty-five (35) day period, but that Brigham Pathology Foundation has begun to take action to cure the material breach, that Brigham Pathology Foundation will pursue such an action with due diligence, and that Brigham Pathology Foundation will give the OIG a timetable for curing the material breach.

If at the conclusion of the thirty-five-day period (or other specific period as subsequently agreed by OIG and Brigham Pathology Foundation), Brigham Pathology Foundation fails to cure the material breach to OIG's satisfaction, subject to the dispute resolution provisions in section XI. of this Agreement, OIG may impose the enhanced stipulated penalty. If OIG elects to impose this enhanced stipulated penalty, OIG shall notify Brigham Pathology Foundation of the imposition of the enhanced penalty in a "Material Breach Letter." The enhanced stipulated penalty shall take effect on the date specified in the Material Breach Letter.

For purposes of this section, a "material breach" is defined as follows: (i) a failure to report a material billing deficiency, take corrective action and pay the appropriate refunds, as provided in section III. B. of this Agreement; (ii) repeated or flagrant violations of the obligations under this Agreement, including, but not limited to, the obligations addressed in section VIII. of this Agreement; or (iii) failure to respond to a Demand Letter in the manner required in section IX of this Agreement.

In connection with the OIG's determination to impose an enhanced stipulated penalty against Brigham Pathology Foundation pursuant to this provision, Brigham Pathology Foundation shall have the right to dispute the OIG's determination in accordance with the agreed upon provisions set forth in section XI. of this Agreement.

## **XI. DISPUTE RESOLUTION**

Upon OIG's delivery to Brigham Pathology Foundation of its Demand Letter or of its Material Breach Letter, and as an agreed upon contractual remedy for the resolution of disputes arising under the obligation of this Agreement, Brigham Pathology Foundation shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. § 1005 as if they applied to the stipulated penalties or an enhanced stipulated penalty sought pursuant to this Agreement. Specifically, the OIG's determination to demand

payment of stipulated penalties or to seek an enhanced stipulated penalty shall be subject to review by an HHS administrative law judge in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. The administrative law judge's decision, in turn, may be appealed to HHS's Departmental Appeals Board ("DAB") in a manner consistent with the provisions in 42 C. F. R. § 1005.21.

Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues to be decided in a proceeding for stipulated penalties under this section shall be the following: (i) whether Brigham Pathology Foundation was in full and timely compliance with the obligations of this Agreement for which OIG demands payment; (ii) whether Brigham Pathology Foundation failed to cure; and (iii) the period of noncompliance. Brigham Pathology Foundation shall have the burden of proving that it was in full and timely compliance and the steps taken to effect the cure, if any. The OIG shall have the burden of proving Brigham Pathology Foundation's failure to cure. For purposes of paying stipulated penalties under this Agreement, and if Brigham Pathology Foundation chooses to seek review in lieu of curing the breach and paying the stipulated penalties, as set forth above, the administrative law judge's decision shall give rise to Brigham Pathology Foundation's obligation to pay. Thus, payment will be due immediately after the issuance of the administrative law judge's decision. Brigham Pathology Foundation's election of its contractual right to appeal to the DAB shall not excuse its obligation to make payment upon the issuance of the administrative law judge's decision.

Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues to be decided in a proceeding for an enhanced stipulated penalty based on a material breach of this Agreement shall be the following: (a) whether Brigham Pathology Foundation was in material breach of one or more of its obligations under this Agreement, (b) whether such material breach was continuing on the date of the Material Breach Letter, and (c) whether the alleged material breach could not be cured within the 35 day period, but that (i) Brigham Pathology Foundation had begun to take action to cure the material breach, (ii) Brigham Pathology Foundation is pursuing such action with due diligence, and (iii) Brigham Pathology Foundation had provided to OIG a reasonable timetable for curing the material breach. For purposes of the enhanced stipulated penalty herein agreed to in the event of material breach of this Agreement, the administrative law judge's decision shall be deemed to make the enhanced stipulated penalty due and owing, if the administrative law judge finds in favor of the OIG. The administrative law judge's decision may be appealed to the DAB in a manner consistent with the provisions in 42 C.F.R. § 1005.21.

All notices required under any of the aforementioned proceedings shall be given to the OIG in accordance with section VI. of this Agreement.

## **XII. COSTS RELATED TO ADDITIONAL AUDITS**

In addition to the obligations assumed by Brigham Pathology Foundation under this Agreement and as described above, if OIG determines that it is necessary to conduct an independent audit or review to determine whether or the extent to which Brigham Pathology Foundation is complying, if at all, with their obligations under this Agreement, Brigham Pathology Foundation agrees to pay for the reasonable costs of any such audit or review by OIG or its duly authorized representative.

## **XIII. UNALLOWABLE COSTS**

It is agreed that all costs (as defined in the Federal Acquisition Regulations ("FAR") 31.205-47) and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395 -1395ddd and 1396-1396v (1997), and the regulations promulgated thereunder) incurred by or on behalf of Brigham Pathology Foundation in connection with (a) the matters covered by this Corporate Integrity Agreement (but not including costs relating to Brigham Pathology Foundation's voluntary Corporate Compliance activities undertaken prior to effective date of this Agreement); (b) the government's audits and investigations of the allegations which are the subject of this Agreement; (c) any of Brigham Pathology Foundation's investigative, defense and collective actions with respect to matters specifically covered by this Agreement, and (d) the negotiation of this Agreement, shall be unallowable costs for government contract accounting purposes and for purposes of seeking reimbursement from either the Medicare, Medicaid or other federal health care programs. Brigham Pathology Foundation shall account separately for these costs for government contract accounting purposes and for purposes of seeking reimbursement from the Medicare and other federal health care programs. Any sums owed by Brigham Pathology Foundation to the United States for payments made to Brigham Pathology Foundation by Medicare and/or Medicaid (federal share) for costs that are unallowable (as defined in this Paragraph) shall be paid by Brigham Pathology Foundation to HHS at HHS' discretion.

## **XIV. NEW LOCATIONS**

In the event that Brigham Pathology Foundation purchases or establishes new business units in which it has a controlling interest after the date of execution of this CIA, Brigham Pathology Foundation shall notify OIG of this fact within thirty (30) days of the date of purchase or establishment. This notification shall include the location of the new operation(s), phone number, fax number, Federal health care program provider number(s) (if any), and the corresponding payor(s)

(contractor specific) that has issued each provider number. All employees at such locations shall be subject to the requirements in this CIA that apply to new employees (e.g., completing certifications and undergoing training).

#### **XV. PRIVILEGES AND DISCLOSURES**

Nothing in this Agreement shall constitute or be construed as a waiver by Brigham Pathology Foundation of its attorney-client or other applicable privileges. Subject to HHS's Freedom of Information Act ("FOIA") procedures, set forth in 45 C.F.R. Part 5, the OIG shall make a reasonable effort to notify Brigham Pathology Foundation prior to any release by OIG of information submitted by Brigham Pathology Foundation pursuant to its obligations under this Agreement and identified upon submission by Brigham Pathology Foundation as trade secrets, commercial or financial information and privileged or confidential under the FOIA rules. Brigham Pathology Foundation shall refrain from identifying any information as trade secrets, commercial or financial information and privileged or confidential that does not meet the criteria for exemption from disclosure under FOIA.

#### **XVI. EFFECTIVE AND BINDING AGREEMENT**

Consistent with the provisions in the settlement agreement pursuant to which this Agreement is entered, and into which this Agreement is incorporated, Brigham Pathology Foundation and the OIG agrees as follows:

1. This Agreement shall be binding on the successors, assigns and transferees of Brigham Pathology Foundation.
2. This Agreement shall become final and binding only upon signing by each respective party hereto.
3. Any modifications to this Agreement shall be made with the prior written consent of the parties to this Agreement.
4. The undersigned signatory for Brigham Pathology Foundation represents and warrants that he is authorized to execute this Agreement. The undersigned OIG signatory represents that he is signing this Agreement in his official capacity and that he is authorized to execute this Agreement.

As Agreed By:

**BRIGHAM & WOMEN'S HOSPITAL PATHOLOGY FOUNDATION, INC.**

June 30, 1999  
Date

R. Cotran  
Ramzi S. Cotran, M.D.  
President

**OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH  
AND HUMAN SERVICES**

6/9/99  
Date

L. Morris  
Lewis Morris, Esquire  
Assistant Inspector General  
Office of Counsel to the Inspector  
General  
Office of Inspector General  
U.S. Department of Health and Human  
Services